DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
OFFICE OF COMMUNICATION
ATLANTA, GA 30333

REQUEST FOR TASK ORDER PROPOSAL

Date Issued: ***June 28, 2005*** **Date Response Due:** ***July 22, 2005***

Questions are due via email to Helen Mitchell, hjm3@cdc.gov by July 11, 2005

Proposals are due via email to Helen Mitchell, hjm3@cdc.gov by July 22, 2005

Request for Task Order Proposal (RFTOP) NO.257: ***CDC 38***

Title: Qualitative Assessment of the Attitudes Mothers Have Toward Collecting Biological Specimens on their Infants and Young Children to Study Risk Factors for Birth Defects and Preterm Delivery

Contract reference: This Request for Task Order Proposal is consistent with the purposes for which the NIH Public Information and Communication Services (PICS) contracts for health communication services were awarded. This RFTOP includes tasks described in the contract as: Communications Research (#1), and Outreach Minority/Underserved Populations (#7).

Page Suggestion:
The contract proposals shall be limited to 15 pages. The cost proposal and other attachments do not count towards the 15 page limit.

Budget format suggestion:
CDC requests that bidders provide budgets using Excel or Word that are broken down by deliverable. A total summary sheet shall be provided which reflects the entire budget proposal for the project. The contractor shall identify each labor category, estimated hours and labor rate by labor category, each indirect (fringe, overhead, G&A, etc.) rate and respective allocation base, travel costs and calculations, other direct costs (ODCs) and description/calculations for each ODC, subcontract/consultant costs and description/calculations for each, profit rate, and other information that the contractor deems necessary. If a subcontractor or consultant agreement is proposed, it should be noted whether it is a cost reimbursable or time and materials agreement. Budgets for any contractor initiated alternative proposals to accomplishing the desired outcomes are welcomed, but should be presented separately and clearly labeled as alternative budget spreadsheets.

Funding Range:

- **X** **Under $100,000 (Estimated to be greater than $50,000)**
- ❑ Over $100,000 but less then $300,000
- ❑ Over $300,000 but less than $500,000

- ❑ Over $500,000 but less than $700,000
- ❑ Over $700,000 but less than $1,000,000
- ❑ Over $1,000,000

Type of Pricing Requested: (check one)

X Cost Plus Fixed Fee

- ❑ Other (Specify) _____

Background:

This project is a new collaboration initiative that will use qualitative research to provide data on the barriers to participation in the collection of biological specimens by mothers on themselves, their infants, and their young children. It is costly to implement the collection of biological specimens into an interview/questionnaire-based study. However, an ever-increasing number of studies include the examination of environmental and genetic interactions to help medical and public health professionals to better understand underlying determinants of health problems and then to develop appropriate interventions. A critical component for studies of gene variants is the collection of biological specimens. Participation and non-participation in the collection of biological specimens is not fully understood. Conducting multiple well-designed focus groups to assess the attitudes of both mothers who participate and mothers who do not participate in the collection of biological specimens will increase the effectiveness of these studies. This information will be useful to many groups at the CDC who are currently collecting biological specimens from infants and their families but with less than optimal response rates and those who are working to implement studies that include the use of biological specimens. CDC scientists from the National Birth Defects Prevention Study (NBDPS) in NCBDDD, the Pregnancy Risk Assessment Monitoring System (PRAMS) in NCCDPHP, and Office of Genomics and Disease Prevention (OGDP) are collaborating on this project with the common goal of gaining insight into the barriers and motivations women have for participating in the collection of biological specimens.

National Birth Defects Prevention Study (NBDPS)

Birth defects are the leading cause of infant death in the United States, accounting for more than 20% of all infant deaths. Birth defects also contribute substantially to illness and long-term disability. The first step in preventing birth defects is identifying their causes. The causes of about 70% of all birth defects are still unknown. The NBDPS is a multi-state, case control study that consists of three components. The first is surveillance used to identify and collect information on infants with major birth defects. The second is interviewing case and control mothers about their pregnancy and medical history to determine environmental risk factors. Third, the NBDPS is currently collecting cheek cells from the case and control infants and their parents in order to identify genetic risk factors. In order to determine significant differences in environmental and genetic risk factors between cases and controls, a large number of infants from a variety of demographic groups are required.

Currently, more than 19,000 mothers have been interviewed. Approximately 70% of mothers who are eligible to participate are interviewed. However, among those interviewed in Atlanta, less than 50% return a biologic sample with the lowest biologics participation among African-American, Spanish speaking Hispanic, and less educated, Caucasian women. Thus,

conducting the focus group discussions in Atlanta will provide the NBDPS with valuable information.

In addition to the low biologic participation rates, DNA yields from cheek cells are less than optimal. The collection of blood should increase DNA yields but may further diminish biologic participation. Currently, all mothers are sent a cheek cell collection kit to administer to themselves, their child, and the child's father. This project will allow the assessment of why mothers do or do not participate in the collection of cheek cells, and will also allow us to determine if there is an alternative form of cell collection that would provide more DNA while maintaining participation rates, and will increase the effectiveness of the NBDPS in collecting biological samples, ultimately leading to better prevention of birth defects.

Pregnancy Risk Assessment Monitoring System (PRAMS)

PRAMS is an ongoing, population-based survey of women who have recently delivered a live born infant. The sample is drawn from state birth certificates using a stratified systematic sampling design. Many states over sample women from minority races or those with low birth weight infants. The final data set includes questionnaire data, selected variables from the birth certificates, and some information from the data collection tracking system. In 2002, the total PRAMS sample for all states was almost 68,000 women.

The questionnaire collects information on many exposures that influence maternal or infant health. However, there is growing evidence that the maternal and fetal genome can alter the effect of these exposures. The evidence is particularly strong for a genetic influence on preterm delivery and for many birth defects, the two leading US causes of infant mortality. Genetic information from biologic specimens would greatly increase the value of PRAMS questionnaire data. Studies of gene-environment interactions, gene-gene interactions, polymorphism prevalence and attributable risk would be possible with PRAMS data, which has a large sample size and demographic information on the women who do not respond.

Women are generally willing to respond to the PRAMS questionnaire; response rates average about 75% and refusals are uncommon. It is unknown, however, what proportion of women would be willing or able to provide usable biologic specimens for themselves and their infants. This project would allow us to investigate the feasibility and best methods of collecting such specimens.

Cross-cutting implications include most areas of CDC addressing infant health. It is expected that an increasing number of CDC studies will need to collect biologic samples and conduct genetic analyses of these samples. Understanding the best approaches for these studies and the potential barriers are critical to the success of these efforts. We will present results in a cross-cutting seminar to CDC staff to ensure interested scientists learn about this project and can apply the information to their topic areas.

Parents are concerned about the occurrence or recurrence of birth defects and preterm delivery and would like to prevent them. Better biologic samples would provide more information on causes and interventions to prevent the occurrence or recurrence of these conditions. Thus, our customer, parents hoping to prevent birth defects and preterm delivery, is a major focus of the proposed project.

Birth defects and preterm delivery both have major health impacts on infant mortality, infant morbidity, life-long disability, and substantial costs to families and society. Gaining the ability to identify the gene variants that are risk factors alone or more often, interact with

modifiable environmental risk factors, has a large impact on the prevention of preterm delivery and birth defects.

Collecting biologic specimens for public health research is expensive and labor intensive. More information on the willingness of people to provide samples and the most effective type of samples would lead to better study designs, thus decreasing costs associated with designing, conducting, and analyzing results from research with poor participation.

Description of work:

The goal of this project is to conduct qualitative research to support ongoing studies and facilitate the planning of new studies at the CDC that involve the collection of biological specimens to study gene variants. The objective of this project is to collaborate with other groups within the CDC to design, implement, and evaluate multiple high-quality focus group discussions with mothers from identified subsets of the population to determine the barriers to participation and the most effective way to motivate their participation in the collection of biological specimens from themselves, their child, and the child's father.

The CDC team desires the research process to answer the following questions:

- What are the mother's beliefs about the benefits and risks of participating in different types of research activities (e.g., phone interview, drug trial, genetic testing, etc.)
- What are the barriers and motivations mothers have to submit biological samples (e.g., buccal cells, giving consent for the use of existing blood spots, providing saliva samples, or allowing a blood sample to be taken)?
- What information would they want to/need to have in order to make an informed decision about providing biological (genetic) samples?
- What is their process for deciding whether to send samples or not? Who is involved in the decision to submit biological samples?
- Who would they turn to provide trustworthy information about whether to provide biologic samples?
- What is the best format for providing them with the information they desire (e.g., phone call, brochure, face-to-face conversation…)?
- Which collection method would mothers choose if they were given options?
- What is clear and/or unclear about current instruction sheets and consent forms for each method?
- What setting for biologic sample collection is more comfortable for them, home or clinic?
- If choosing a collection method that requires an outside collector, what qualities (gender, degree, etc) are preferred in the collector?
- What is fair remuneration for submitting biologic samples?

CDC is interested in conducting six focus groups to more clearly understand NBDPS research participant's perceptions and decision-making about whether to send requested biologic (genetic) samples. CDC is looking for an *experienced* contractor who specializes in conducting focus groups and analyzing the resulting data using robust methods, including the use of qualitative software. CDC requests the following services for each part of this project:

CDC requests a contractor to conduct six focus groups (ideally each with 12 participants). CDC proposes the following segmentation for the groups and will provide a list of eligible participants:

African-American women who have completed an NBDPS phone interview and submitted biological samples in the last 24 months	African-American women who have completed the NBDPS phone interview, been sent biological sample kits, but NOT submitted biological samples in the last 24 months	Women who have completed the NBDPS phone interview and who had infants with low birth weights in the last 24 months.
2 focus group discussions	2 focus group discussions	2 focus group discussions

1. Budget and Timeline

Because CDC must request amendments to existing IRB and OMB approvals for doing this research, a timeline is included below. CDC requests that contractors provide line-item budgets associated with all deliverables and a detailed timeline associated with all tasks and deliverables during the period of performance, keeping the included timeline in mind.

NOTE: To be consistent with other aspects of NBDPS, CDC requests that the contractor build into their budgets the following monetary incentives (via a money order or petty cash) for participants of the focus group discussions: Participation in focus group - $50 at focus group facility; Childcare - $50 money order with letter confirming participation in focus group; and transportation - $20 cash or money order for a courtesy ride, public transportation, or mileage to and from focus group facility or actual cost (petty cash) for the contractor to schedule and pay for round trip taxi.

Anticipated Timeline

June 2005 (CDC Activities)

- Submit RFTOP to NIH PICS contract to acquire contractor services
- Submit IRB amendment #1 (for recruitment procedures) to existing CDC protocol

July – August 2005 (CDC Activities)

- Receive proposals, conduct review panel, select contractor, award RFTOP
- IRB amendment #1 review / approval received
- Submit OMB amendment to existing CDC protocol (with study protocol outlined and accompanying instruments)

September – November 2005 (Contractor and CDC Activities through 2/28/07)

- Contractor target start date: 9/1/05
- Meeting with contractor for introductions and review scope of work and timeline
- Obtain contractor's input on the draft moderator's guide and study protocol
- Contractor will need to submit the study protocol through their organization's IRB review process and obtain necessary approvals.
- CDC submits study protocol (with final moderator's guide; analytic plan, etc.) to IRB (amendment #2)

December 2005 – January 2006

- IRB amendment #2 review / approval received

February – April 2006

- Receive OMB approval
- CDC provides list of eligible participants.

June – October 2006

- Recruitment begins and focus groups conducted
- 1st draft report due to CDC by October 15th
- CDC reviews and provides feedback by November 15th

November 2006

- Final report due by December 15th (incorporating feedback from CDC staff)

January 2007

- Follow up / close out

2. Logistics and Recruitment Plan

- CDC will provide the contractor with the contact information of eligible NBDPS study participants. Information provided will include the participant's name, address, telephone number, and which segment they represent. From this list, the contractor is responsible for recruiting approximately 15 different women for each focus group with a goal of 12 different women actually participating in each of the six focus groups. Therefore, the target is 72 women total with a goal of 12 women per focus group with a minimum of 6 women to hold a focus group. The contractor will work with CDC if a specific focus group will be or is under attended.
- Conduct a total of 6 focus groups in Atlanta. CDC requests locations that are convenient for the target audience of this research specifically women living in the five-county catchment area of NBDPS. The five counties include: Fulton, Dekalb, Gwinnett, Cobb, and Clayton.
- Locate and secure focus group facilities in Atlanta. Contractor should have contacts, offices, or the ability to conduct focus groups ensuring all details are attended to throughout the data collection process. Ideally, focus group locations would have the ability for researchers to observe proceedings via one-way mirrors.
- Locations of focus groups should be accessible to the population recruited and have access to public transportation, if possible.
- With CDC, develop appropriate telephone recruitment script for use in contacting eligible NBDPS participants.

Proposals should provide logistics and recruitment plans for all three segments in Atlanta, GA. The plan should include the following:

a. Description of the location and the facilities (populations served, accessibility, etc.).
b. Ability to conduct focus groups within timeframe proposed (with letters of support, if applicable).
c. Detailed description of proposed recruitment timeline.
d. Detailed description of proposed recruitment efforts

3. Implementation

- Work with CDC to develop and finalize moderator guides for each audience segment.
- Conduct 6 focus groups with a trained, experienced moderator(s) who has skills conducting qualitative research with African American women, especially mothers of young children. It is strongly recommended that contractor use only one moderator to conduct all focus groups in order to ensure consistency among groups.
- Audio tape record of all focus group sessions.
- Transcripts of all focus groups (in Word format) which must be made available to CDC unconditionally.

4. Progress Reports

- Provide a strategy for ensuring optimal communication between Contractor and CDC throughout duration of task order.
- Provide monthly reports electronically to CDC detailing the progress and status of each deliverable.

5. Analyses

- Conduct top-lines from each focus group within one week of each focus group.
- Conduct qualitative analyses on focus group transcripts using qualitative software such as NUD*IST and/or ATLAS-TI.
- Provide data codebooks and a copy of a cleaned data set to CDC.
- CDC will have unconditional access to all data.

6. Report

- Provide draft qualitative data analysis report describing motivations and barriers to submitting biologic samples no later than October 15, 2006.
- Provide final qualitative data analysis report describing motivations and barriers to submitting biologic samples no later than December 15, 2006.
- Provide transcripts of all focus groups within two weeks of each focus group.
- Provide top-lines from each focus group within one week of each focus group.

Items from CDC appropriate for preparation of proposals:
None.

Items from CDC appropriate for task completion:

1. A list of eligible participants from NBDPS. Data will include participant's name, address, telephone number, and which segment.
2. CDC will initiate IRB and OMB amendments to the current NBDPS protocols. The successful contractor will need to develop a human subjects protocol and obtain IRB approval as well. The successful contractor should be knowledgeable of the IRB process and preferably have an assigned IRB board with a current Federalwide Assurance (FWA) number.

Deliverables:

Deliverable	*Due Date*
1. IRB approval. Before conducting the focus groups, the contractor shall work with CDC to develop a human subjects protocol in Word format and obtain IRB approval. (80% of the contract award amount will be restricted until the contractor has obtained IRB approval.)	November 2005
2. Recruitment plan. Develop a plan, including methods and timeline, for obtaining participation from NBDPS study participants that meets CDC's segmentation requirements. Recruit approximately 15 women for each focus group. No more than 12 women and no less than 6 women should actually participate in each focus group.	November 2005
3. High-quality focus group discussions (6) completed with identified audience segments.	September 2006
4. Audiotapes from all focus group discussions. Each audiotape must be labeled clearly with the segment, location, and date of the focus group.	October 2006
5. Cleaned transcripts from all focus group discussions in a Microsoft Word format.	October 2006
6. A moderator's top line report from each focus group discussion within one week of focus group discussion.	Weekly between July–Sept. 2006 when focus groups are conducted
7. A final report which includes analysis of transcripts using qualitative software (including codebook and data set) as well as a synthesis of all top line reports. All of these items should come to CDC in electronic form. Additionally, a hard copy of the final report, codebook, and top line synthesis should be provided.	Draft – Oct. 15, 2006 Final--Dec 15, 2006
8. Monthly progress reports in Word and/or Excel format should be submitted electronically to CDC.	Monthly

Contractors should please note that all products developed under this task order are the property of CDC. Additionally, the contractor shall maintain the confidentiality of the participants.

Period of Performance:
The performance period is 18 months with no option periods and begins with date of award. The start date is estimated to be September 1, 2005 and the overall end date is February 28, 2007.

Special Clearances:
Check all that apply:
_*x*__ OMB
_x__ Human Subjects
___ Privacy Act

Production Clearances:
___ 524 (concept)

___ 524a (audiovisual) ___ 615 (printing)

Evaluation Criteria:

A. Award: This task order will be awarded to the contractor whose proposal is considered to be the most advantageous to the Government, price and other factors identified below considered. Technical factors will be more important in the evaluation.* The Government will not make an award at a significantly higher overall cost to the Government to achieve only slightly superior performance.

B. Technical Evaluation:
Technical evaluation criteria for this RFTOP are as follows:

Criterion	Points or relative Value of criterion
Technical Approach	35
Staffing and Management	30
Similar Experience	35
Total	**100 points**

Technical Approach:
Contractors are to provide a discussion of their technical approach for providing the services required for this task order. These criteria will be evaluated according to the soundness, practicality, and feasibility of the contractor's technical approach for providing the services required for this task order. Attention will be given to Contractor(s) ability to conduct and analyze qualitative health research with African-American women of child-bearing age in the U.S. Specifically, contractors should demonstrate the ability to conduct focus groups on complex, sensitive topics and complete all deliverables within the given time frame.

Staffing and Management:
Contractors should offer staff that has experience with successfully conducting focus groups and analyzing qualitative data that achieve desired results. Staff will collaborate closely with CDC staff. Research experience with urban and suburban African American women of childbearing age is preferred.

Contractors are to provide (1) a staffing plan that demonstrates their understanding of the labor requirements for this task order; and (2) a management plan that describes their approach for managing the work, to include subcontract management if applicable, (3) resumes from key personnel, and (4) letters of intent from potential sub-contractors.

This criterion will be evaluated according to the soundness, practicality, and feasibility of the applicant's staffing and management plans for this task order. Preference will be given to contractors who propose staff who have experience conducting high quality qualitative research.

Similar Experience:
Contractor should provide no more than three examples of previous work completed within the last three years that demonstrate the Contractor's ability to manage a project that is similar in complexity and size, as well as within similar time frames, to this project.

Each example should include a brief discussion of the project, a description of the personnel involved, and any unique facets or findings from the project. Actual budget and time-line for development and delivery of the plan should be described, if possible. Contact name of client and contact phone number should be provided in the one page narrative.

Contractors demonstrating superior ability to conduct and analyze high quality qualitative research as evidenced by three strong examples of previous work will be favored. Examples describing focus group work among African-American women of childbearing age will be favored. Contractors who demonstrate an ability to perform the tasks described in the scope of work within the client's budget and/or time line and that receive complimentary evaluations from former client contacts will be favored.

C. Cost Evaluation: A cost analysis of the cost proposal shall be conducted to determine the allowability and reasonableness of the contractor's cost proposal.

Technical Monitor:
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